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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,425	01/26/2001	Xaveer Van Ostade	4644US	8053

7590

10/18/2002

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EXAMINER

LI, RUIXIANG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 10/18/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/771,425

Applicant(s)

OSTADE ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14-19 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14-19 and 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 August 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **I. Status of Application, Amendments, and/or Claims**

The amendment filed in Paper No. 11 on August 29, 2002 has been entered in full. Claims 8, 11, and 15 have been amended. Claims 1-11, 14-19, and 21-23 are pending and are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **II. Priority Document**

The foreign priority document, EPO98202528.0, filed on 07/28/1998, has been received by the Office.

### **III. Withdrawn Objections and/or Rejections**

The objection to Drawings, as set forth at page 2 of the previous Office Action (Paper No. 9, May 29, 2002), has been withdrawn in view of submitted corrected drawings.

The objection to Claim 8 for minor informality, as set forth at page 9 of the previous Office Action (Paper No. 9, May 29, 2002), has been withdrawn in view of applicants' amendment of Claim 8.

### **IV. Claim Rejections Under 35 U. S. C. § 112, 2<sup>nd</sup> Paragraph**

The rejection of Claims 11 and 15-19 under 35 U. S. C. § 112, 2<sup>nd</sup> paragraph, as set forth at page 3 of the previous Office Action (Paper No. 9, May 29, 2002), remains.

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Claims 11 and 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is indefinite because of the use of the word, "interfere", which might mean, either "inhibit" or "enhance". It is suggested that the word "interfere" be replaced with "inhibit".

Claims 15-19 are indefinite because the steps recited by the methods do not necessarily achieve the goal set forth in the claim preamble. It is unclear how these steps will be able to screen for orphan receptors **and** unknown ligands at the same time.

In addition, Claim 16 is indefinite because it is unclear what "series of compounds" means.

#### **V. Claim Rejections Under 35 U. S. C. § 103 (a)**

(i) The rejection of Claims 1-6, 14, and 21-23 under 35 U.S.C. 103(a) as being unpatentable over Muthukumaran et al. (*IDS, J. Biol. Chem.* 272:4993-4999, 1997) in view of Trueheart et al. (*IDS, WO 98/13513*, April 2, 1998), set forth at pages 4-5 of the previous Office Action (Paper No. 8, January 25, 2002), remains.

Applicants argue (i) that the Office action has not indicated where a motivation or suggestion exists in the cited references to combine them; and (ii) that because no reasonable expectation of success exists in combining the cited references, a *prima facie* case of obviousness cannot be established. This has been fully considered but is not deemed to be persuasive for the following reasons.

First, the previous Office action (Paper No. 8, January 25, 2002) clearly indicates the motivation of combining the teaching of Muthukumaran et al. with the teaching of Trueheart et al., that is, endogenous expression of polypeptides in a cDNA library allows rapid screening of large numbers of polypeptides as taught by Trueheart et al. (page 3, last paragraph). Applicants argue that this is merely a benefit stated by the Trueheart et al. and that no suggestions or motivation exists in Trueheart et al. to use a chimeric receptor. Applicants further argue that if the idea of combining chimeric receptors with autocrine loops were obvious, Trueheart et al. would have cited the use of chimeric receptors in the extensive disclosure. The Examiner disagrees because it is the benefit of allowing rapid screening of large numbers of compounds that motivates one skilled in the art to combine the teaching of Muthukumaran et al. with the teaching of Trueheart et al. It is unnecessary that the claimed invention be expressly suggested in any one or all of the references to justify combining their teachings; rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art (*In re Keller*, 642 F.2d 413, 288 USPQ 871 (CCPA 1981)).

Second, while it may be true the chimeric receptor of Muthukumaran et al. might not be functional in the yeast cells, the autocrine loops in yeast cells taught by Trueheart et al. would assume to work in CHO-B7 and CHO-16-9 cells that express chimeric receptors, as taught by Muthukumaran et al., absence of evidence to the contrary. One skilled in the art would be able to combine the autocrine loops taught by Trueheart et al. with the chimeric receptors in CHO-B7 and CHO-16-9 cells taught by Muthukumaran et al. with a reasonable expectation of success.

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(ii) The rejection of Claims 7, 8, and 10 under 35 U.S.C. 103(a) as being unpatentable over Muthukumaran et al. in view of Trueheart et al. as applied to claims 1-6, 14, and 21-23 above, and further in view of Pellegrini et al. (*IDS, Molecular and Cellular Biology* 9:4605-4612, 1989), set forth at pages 5 and 6 of the previous Office Action (Paper No. 8, January 25, 2002), remains.

Applicants argue (i) that the statement provided in the Office Action does not provide a suggestion or motivation to combine the cited references, but merely indicates the functionality of the 6-16 promoter; (ii) Pellegrini et al. do not suggest or motivate the use of a chimeric receptor, an autocrine loop or a reporter system.

This has been fully considered but is not deemed to be persuasive because it is not necessary that the claimed invention be expressly suggested in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art *In re Keller*, 642 F.2d 413, 288 USPQ 871 9ccpa 1981). In addition, only a reason, suggestion or motivation needs to appear in the cited prior art in order to combine references under 35 U.S.C. 103. *Pro Mold Tool Col. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996). In the instant case, the motivation is that the 6-16 promoter can be fused to a variety of different genes and are tightly regulated by interferon, as shown by Pellegrini et al, in the *gpt* gene in 2fTGH cells (page 4610, 1<sup>st</sup> paragraph of Discussion).

(iii) The rejection of Claim 9 under 35 U.S.C. 103(a) as being unpatentable over being unpatentable over Muthukumaran et al. in view of Trueheart et al. as applied to

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claims 1-6, 14, and 21-23 above, and further in view of Mizushima et al. (Nucleic Acids Research, 18:5322, 1990), set forth at page 6 of the previous Office Action (Paper No. 8, January 25, 2002), remains.

The rejection of Claims 11 and 15-18 under 35 U.S.C. 103(a) as being unpatentable over Trueheart et al. in view of Muthukumaran et al., set forth at pages 6-8 of the previous Office Action (Paper No. 8, January 25, 2002), remains.

The rejection of Claim 19 under 35 U.S.C. 103(a) as being unpatentable over Trueheart et al. in view of Muthukumaran et al. as applied to claims 11 and 15-18 above, and further in view of Watowich et al. (*Proc. Natl. Acad. Sci. USA* 89:2140-2144, 1992), set forth at pages 8-9 of the previous Office Action (Paper No. 8, January 25, 2002), remains.

Applicants' argument about the lack of motivation to combine the respective teachings has been fully considered but is not deemed to be persuasive for the reasons set forth above and in the previous Office Action (pages 6-9 of Paper No. 8, January 25, 2002).

## **VI. Conclusion**

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35



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U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li  
Examiner  
October 11, 2002

A handwritten signature in cursive script that reads "Elizabeth C. Kemmerer". The signature is written in black ink and has a fluid, connected style.

ELIZABETH KEMMERER  
PRIMARY EXAMINER